A Nonsurgical Approach to the Management of Patients With Lumbar Radiculopathy Secondary to Herniated Disk: A Prospective Observational Cohort Study With Follow-Up

Donald R. Murphy, DC,[a,b,c] Eric L. Hurwitz, DC, PhD,[d] and Ericka E. McGovern, DC[e]

Abstract

Objective: This study presents the outcomes of patients with lumbar radiculopathy secondary to disk herniation treated after a diagnosis-based clinical decision rule.

Methods: A prospective observational cohort study was conducted at a multidisciplinary, integrated clinic that includes chiropractic and physical therapy health care services. Data on 49 consecutive patients were collected at baseline, at the end of conservative, nonsurgical treatment and a mean of 14.5 months after cessation of treatment. Disability was measured using the Bournemouth Disability Questionnaire (BDQ) and pain using the Numerical Rating Scale for pain. Fear beliefs were measured with the Fear-Avoidance Beliefs Questionnaire (FABQ). Patients also self-rated improvement.

Results: Mean duration of complaint was 60.5 weeks. Mean self-rated improvement at the end of treatment was 77.5%. Improvement was described as "good" or "excellent" in nearly 90% of patients. Mean percentage improvement on the BDQ was 60.4%. Numerical Rating Scale improved 4.1 points and FABQ improved 4.8 points. Clinically meaningful improvements in pain and disability were seen in 79% and 70% of patients, respectively. Mean number of visits was 13.2. After an average long-term follow-up of 14.5 months, mean self-rated improvement was 81.1%. "Good" or "excellent" improvement was reported by 80% of patients. Mean percentage improvement in BDQ was 67.4%. Numerical Rating Scale improved 4.2 points and FABQ 4.5 points. Clinically meaningful improvements in pain and disability were seen in 79% and 73% of patients, respectively.

Conclusions: Management based on the decision rule yielded favorable outcomes in this cohort study. Improvement appeared to be maintained over the long term. (J Manipulative Physiol Ther 2009;32:723-733)

Key Indexing Terms: *Lumbar Region; Radiculopathy; Disk, Herniated; Lumbar Manipulation; Sciatica; Chiropractic; Delivery of Health Care, Integrated*

Lumbar radiculopathy secondary to herniated disk (LRSHD) is a common and often disabling problem. Lifetime prevalence has been estimated to be 35% in men and 45% in women.[1] It has been estimated that 90% of LRSHD occurs at either the L4-5 or L5-S1 levels.[2]

Although surgery is often recommended for this disorder, it has been estimated that only 2% to 4% of patients with LRSHD have indications for surgery.[3] Thus, most patients are best treated nonsurgically. Various nonsurgical treatments have been recommended for this condition,[4] but little data have been generated showing substantial improvement with any particular approach.

A diagnosis-based clinical decision rule (DBCDR) for patients with spinal pain has recently been developed,[5,6] designed to allow clinicians to identify the key factors that are present in each patient to make treatment decisions based on these factors. Preliminary evidence suggests that this approach may be effective in patients with cervical radiculopathy,[7] lumbar spinal stenosis,[8] pregnancy-related lumbopelvic pain,[9] and chronic work-related neck/arm

[a] Clinical Director, Rhode Island Spine Center, Pawtucket, RI.
[b] Clinical Assistant Professor, Department of Community Health, Warren Alpert Medical School of Brown University, Providence, RI.
[c] Adjunct Associate Professor, Department of Research, New York Chiropractic College, Seneca Falls, NY.
[d] Associate Professor of Epidemiology, Department of Public Health Sciences and Epidemiology, John A. Burns School of Medicine, University of Hawaii, Mānoa, Hawaii.
[e] Staff Chiropractic Physician, Rhode Island Spine Center, Pawtucket, RI.
Submit requests for reprints to: Donald R. Murphy, DC, Rhode Island Spine Center, 600 Pawtucket Avenue, Pawtucket, RI 02860 (e-mail: *rispine@aol.com*).
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pain.[10] The outcome of treatment according to the DBCDR in patients with LRSHD has not yet been evaluated.

The primary objective of this study was to prospectively assess, using rigorous outcome measures, treatment results according to the DBCDR of patients with documented LRSHD. The secondary objective was to estimate the effect of changes in fear-avoidance beliefs on pain and disability outcomes.

Methods

The study protocol was approved by the Institutional Review Board of New York Chiropractic College, Seneca Falls, NY. It was also reviewed by the Health Insurance Portability and Accountability Act compliance officer of the facility at which the data were gathered and was deemed to be in compliance with Health Insurance Portability and Accountability Act regulations. All subjects signed informed consent forms, agreeing to have their data included in the study. Data were gathered on a prospective cohort of consecutive patients seen at the Rhode Island Spine Center, Pawtucket, RI (a multidisciplinary, integrated clinic that includes chiropractic and physical therapy services), between March 8, 2004, and December 4, 2006, who were diagnosed with LRSHD.

Inclusion and Exclusion Criteria

Patients were included in the study if they (1) had lower extremity pain with or without low back pain (LBP) clinically determined to be arising from LRSHD and (2) had at least one follow-up reexamination (typically performed every 3-4 weeks). Also, to be included, each patient required magnetic resonance imaging (MRI) or computed tomography (CT) documentation of a disk herniation as well as reproduction of the leg pain with neurodynamic tests designed to identify nerve root pain.[11] To qualify as having reproduction of pain with neurodynamic tests, there had to be not only pain on straight leg raise or femoral nerve stretch test, but also appropriate findings with sensitizing and localizing maneuvers.[11] For example, reproduction of pain with straight leg raise had to be worsened by ankle dorsiflexion and head flexion, and lessened by ankle plantar flexion.

Other inclusion criteria included 17 years or older, no contraindications to the study treatments, and ability to speak English. Patients were excluded if their symptoms were determined to be related to a condition other than LRSHD, such as systemic illness or spinal stenosis from bony encroachment; if they were determined to be a surgical case at the outset; if there were contraindications to study treatments such as cancer, blood dyscrasias, large abdominal aortic aneurism, fracture, dislocation, or spinal infection; inability to communicate well in English; medicolegal involvement (ie, workers' compensation and personal injury cases); and a Waddell's nonorganic signs score of 5/5. Surgical cases at the outset were defined as those with signs of cauda equina syndrome determined by history and examination or those with motor loss greater than 3/5 based on neurologic examination, using the standard grading system ranging from 0 (no visible contraction) to 5 (normal strength).[12]

Interventions

Each patient was examined and treated in the manner that would occur in ordinary clinical circumstances at the Rhode Island Spine Center. Details of this DBCDR approach are provided elsewhere.[5,6] The process starts with seeking to establish a working diagnosis. This process is founded on the "3 essential questions of diagnosis," which are as follows:

1. Are the symptoms with which the patient is presenting reflective of a visceral disorder, or a serious or potentially life-threatening disease?
2. From where is the pain arising?
3. What has gone wrong with this person as a whole that would cause the pain experience to develop and persist?

The history and examination process was undertaken in an attempt to seek answers to these 3 questions. In response to question 1, if visceral disease or serious or potentially life-threatening illness was strongly suspected, the patient was further worked up accordingly or referred to another physician for evaluation.

Question 2 considers 4 signs that most commonly reflect the underlying pain-generating tissue: centralization signs, segmental pain provocation signs, neurodynamic signs, and muscle palpation signs. In response to question 2, treatment of the suspected pain source(s) was undertaken. By definition, all patients had neurodynamic signs, reflective of nerve root pain. However, consideration was given to other potential pain sources because more than one pain source was found in many cases. Treatment in response to question 2 focused on distraction manipulation, neurodynamic techniques, end-range loading maneuvers, joint manipulation, and myofascial techniques.[13]

Distraction manipulation has been shown to decrease intradiscal pressure[14,15] to be effective in patients with LBP in general and to be more effective than an active exercise protocol in patients with lumbar radiculopathy.[16] Neurodynamic techniques[11] are theorized to mobilize and desensitize painful nerve roots.[17] End-range loading maneuvers may be used if the patient's symptoms are found to centralize upon end-range loading examination.[18]

Joint manipulation may be used if segmental provocation maneuvers reproduced all or part of a patient's pain and centralization of pain was not found on end-range loading examination.[19,20] This treatment typically involved lying the patient in the side posture position with the side

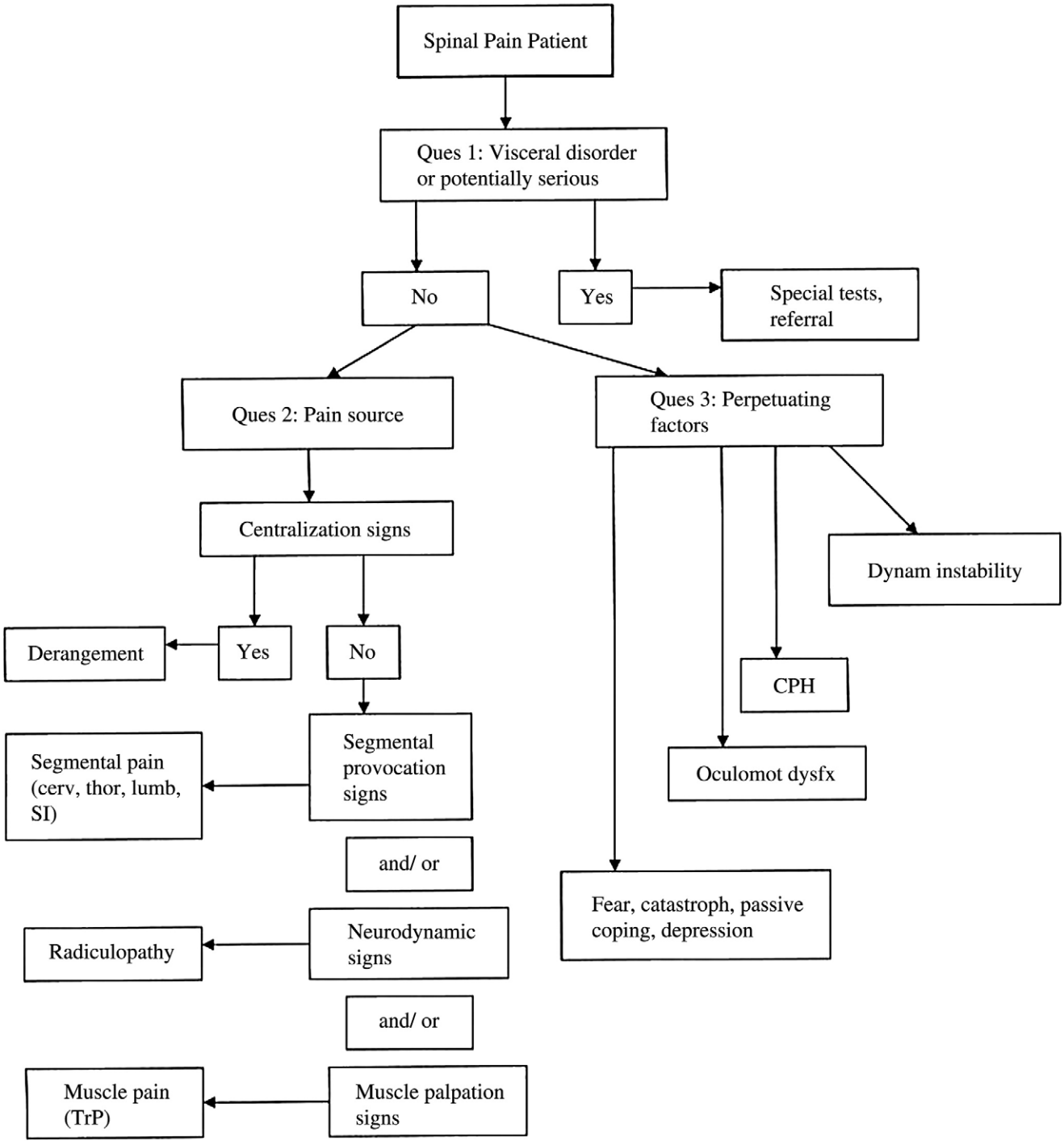

Fig 1. *Diagnostic algorithm using the DBCDR.*

being treated up and applying either a high-velocity, low-amplitude "thrust"[21] or a low-velocity muscle energy maneuver.[22] Myofascial techniques, such as ischemic compression or muscle lengthening procedures,[23] could be used if myofascial trigger points were found that did not spontaneously resolve when the other suspected pain sources were treated.

Question 3 considered factors that are suspected to perpetuate the pain experience and interfere with recovery. These factors include dynamic instability (impaired motor control), central pain hypersensitivity (CPH), and psychologic factors such as fear, catastrophizing, passive coping, and depression. If dynamic instability was found, rehabilitation focused on stabilization exercise training.[24] If CPH,

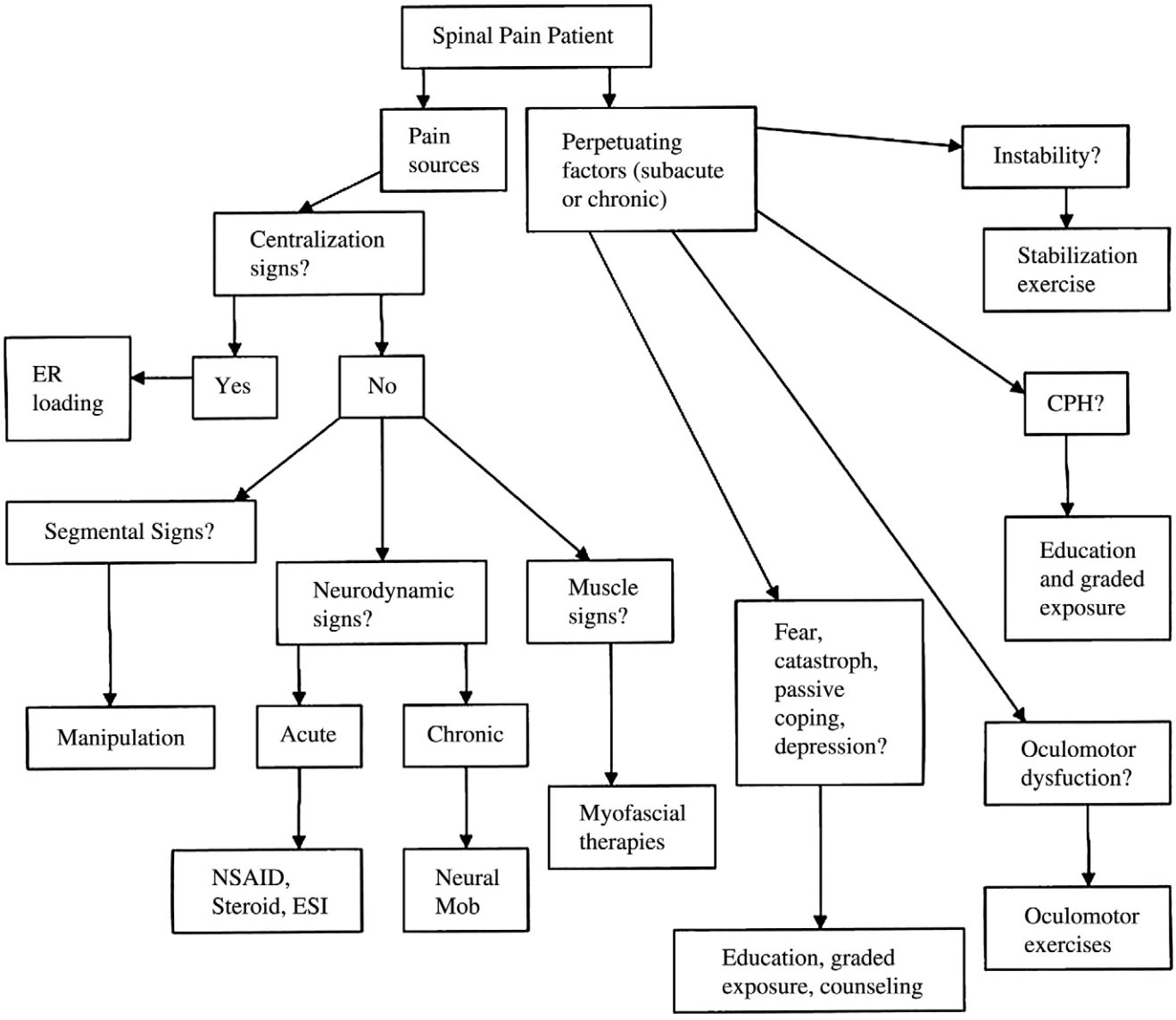

Fig 2. *Management algorithm using the DBCDR.*

fear, or catastrophizing was found or suspected, education was targeted at whichever of these factors was present and graded exposure[25] was used. If passive coping was present, the patient was taught active coping strategies such as learning to use exercise to self-manage the condition and learning to focus on function rather than solely on symptoms. If depression was present, this was monitored, and if it did not spontaneously improve along with clinical improvement, the patient was referred for specialist intervention.

Exercise was implemented from the beginning in most cases. In those in whom centralization signs were found, this focused on end-range loading exercises in the direction of centralization.[18] In some acute cases, centralization could not be identified initially but was identified after resolution of the acute phase. In those patients in whom signs of dynamic instability were found, stabilization exercise was typically started after the initial treatment of the suspected pain source. However, in no case was exercise deferred until the patient was pain free. On the contrary, because an important educational point was that movement and activity should be pursued even in the presence of pain, exercise was instituted well before pain resolution.

Although the approach was comprehensive from a conceptual standpoint, each patient's intervention was minimalist in nature—only those treatment approaches that were deemed necessary on the basis of specific clinical findings were applied. The decision as to which treatments were to be used in any particular patient was made on an individual basis. All treatment was provided in the context of a cognitive-behavioral approach.[26] That is, from the

beginning, with every patient, messages were communicated to encourage the patient to maintain as normal an activity level as possible, that LRSHD is not a "catastrophe" but is a treatable condition with a favorable prognosis, and that movement and activity, particularly work, were not only safe, but also therapeutic.

Imaging, such as MRI, or special tests, such as electromyography or blood tests, were sought if required for clarification of the diagnosis.

Although the frequency and duration of care was determined on an individual basis, each patient was generally seen 2 to 3 times per week for 3 weeks initially, after which, the first reexamination was performed, including assessment of the primary outcomes. This was typically followed by either continued frequency of 2 times per week or a reduction in frequency to 1 time per week, though some patients who were fully recovered were released to 3-week follow-up after the first reexamination.

All patients were initially examined by a chiropractic physician (DRM or EEM) who formulated a working diagnosis and a management strategy based on this working diagnosis. In all cases, the diagnosis was made according to the DBCDR, which consists of historical factors and examination procedures most of which have known inter-examiner reliability as well as validity. The same diagnostic algorithm was followed in all cases (Fig 1). The management strategy was then implemented by a chiropractic physician/physical therapist team. The management strategy was based on the diagnosis in each case, and the approach was uniform across patients (Fig 2).

Outcome Measures

The primary outcome measures were the Bournemouth Disability Questionnaire (BDQ)[27] and the Numerical Rating Scale (NRS) for pain intensity.[28] Secondary outcome measures were patient self-rating of outcome (excellent, good, fair, poor, none) and the subjective percentage improvement (0% signifying no improvement and 100% signifying complete recovery). Criteria for clinically meaningful improvements in pain and disability were set a priori.[28,29]

Other Measures

The Activity subscale of the Fear-Avoidance Beliefs Questionnaire (FABQ-Act)[30] was also provided to each patient. These measures were completed at baseline and at each reexamination, which typically occurred approximately every 3 to 4 weeks until the end of clinical care.

Other data gathered included age, sex, duration of symptoms, primary diagnosis, secondary diagnosis (if any), rheumatologic or orthopedic conditions affecting the spine, number of treatment visits, lumbar intervertebral levels affected based on MRI or CT, history of lumbar surgery and type, types of treatments applied, and complications to any study treatments.

Table 1. *Baseline characteristics*

Variable	Mean	Median	SD	Range
Age[a]	47.8	44.5	14.0	22-80
Duration of symptoms (wk)[b]	55.9	9.0	127.3	<1 to 676
BDQ score at baseline[c]	46.0	48.0	15.7	19-70
NRS score at baseline[c]	7.3	8.0	2.2	4-10.0
FABQ-Act score at baseline[b]	20.5	20.0	7.4	9-30

[a] n = 60.
[b] n = 55.
[c] n = 58.

These data were gathered prospectively as part of the usual patient management process at the facility at which the treatment was provided. Data were gathered at baseline and at regular intervals throughout the process of care, typically every 3 weeks. The data reported here are those collected at baseline, at the end of treatment, and at long-term follow-up. Long-term follow-up was carried out by mailing the outcome measurement questionnaires to each subject with a cover letter requesting that the questionnaires be filled out and sent back.

Statistical Analysis

Descriptive statistics were used to characterize the study population at baseline and at reexamination. Frequencies and percentages were computed for categorical variables; mean values, SDs, medians, and ranges were computed for continuous variables. Baseline to reexamination and long-term follow-up change scores were computed for each primary outcome measure and reported in terms of both absolute and percentage changes. General linear modeling was used to estimate the effects of changes in fear-avoidance beliefs on pain and disability outcomes. Age, sex, and duration of symptoms were considered as covariates in initial models, but because estimates from models that included these variables were essentially the same as the unadjusted estimates, only the latter (unadjusted) estimates are presented. Data management and statistical analyses were conducted with Microsoft Excel (Microsoft Inc, Redmond, Wash) and SAS version 9.1(SAS Institute Inc, Cary, NC).

Results

Table 1 presents the baseline characteristics. Baseline data were gathered on 60 patients. The mean duration of symptoms was 55.9 weeks. Centralization of symptoms during end-range loading examination[18] was seen in 61.5% of subjects. Peripheralization was seen in 7.7%. In 30.8% of subjects, no clear centralization or peripheralization was found. The most common direction of centralization was extension (n = 23) followed by right side glide (n = 4), left

Table 2. *Levels of disk herniation*

Level	L1-2	L2-3	L3-4	L4-5	L5-S1
n	2	4	10	25	25

Table 3. *Outcomes from baseline to end of treatment*

	Last reexamination			
Variable	Mean	Median	SD	Range
Self-rated improvement (%)[a]	77.2	20.6	80	10 to 100
BDQ score[b]	17.1	14.4	13.5	0 to 51
NRS score[a]	3.0	2.2	3	0 to 8
Change in BDQ[b]	28.7	18.4	27	−4 to 70
Change in NRS[a]	4.0	2.7	3.5	0 to 9
% change BDQ[b]	62.0	68.0	31.0	11.0 to 100.0
% change NRS[a]	62.0	67.0	34.5	−20.0 to 100.0
Change FABQ score[c]	4.8	7.8	4	−12 to 21
No. of treatments to a DC[d]	7.7	4.4	7	0 to 20
No. of treatments to a PT[d]	4.9	5.1	4.5	0 to 22

DC, Doctor of chiropractic; *PT*, physical therapist.
[a] n = 44.
[b] n = 46.
[c] n = 45.
[d] n = 52.

side glide (n = 2), and flexion (n = 1). In 2 patients, centralization occurred with end-range loading in 2 different directions. By definition, all patients had MRI-confirmed disk herniation (no cases involved the use of CT) and reproduction of pain using clinical examination procedures that have known reliability and validity.[31-35] The levels of herniation are listed in Table 2. Multiple levels of involvement were found in 6 patients. Because this was a practice-based study, no follow-up MRIs were ordered, because these were not deemed clinically indicated in any patient.

All but 2 patients were treated with distraction manipulation. Although evidence suggests that precise specificity with manual treatments is unlikely to be achieved consistently,[36] every attempt was made to direct the treatment as close to the involved disk level as possible. Six patients were treated with joint manipulation, all of which was of the high-velocity, low-amplitude "thrust" type. One patient was treated with joint manipulation but not distraction manipulation. In one patient, neither distraction nor joint manipulation was used. The decision to use joint manipulation was based on clinical findings suggestive of zygapophyseal pain[20,37] or sacroiliac pain.[19,37,38] Joint manipulation was directed to the lumbar zygapophyseal joints in 3 patients, the sacroiliac joints in 2 patients, and the lower thoracic spine in 1 patient. All those patients whose symptoms centralized on examination were provided with end-range loading exercises in the direction of centralization.[18] Some form of neural mobilization[11] was performed with all patients. All patients were provided with a basic trunk muscle cocontraction exercise,[39] and a complete spinal stabilization exercise program[24] was provided in 40 patients (66.6%). Eight patients were referred for epidural steroid injection (ESI).

Table 4. *Outcomes from baseline to long-term follow-up*

	Long-term follow-up			
Variable	Mean	Median	SD	Range
Self-rated improvement (%)[a]	81.1	22.0	90	10 to 100
Change in BDQ[a]	31.0	20.2	30	−7 to 63
Change in NRS[a]	4.2	2.9	4	−1 to 9
% change BDQ[a]	60.4	36.8	85	−11.0 to 100.0
Change FABQ score[b]	4.5	9.5	6	−15 to 20

[a] n = 37.
[b] n = 27.

Data on the main results from baseline to the end of treatment were collected on 46 patients (76.6%). These are presented in Table 3. Mean improvement in BDQ score was 28.7 points (from 45.8 to 17.7). The mean percentage improvement in scores on the BDQ was 62%. This well exceeds the threshold of 47% for clinically meaningful improvement using the BDQ.[29] Using this threshold as the cutoff, clinically meaningful improvement in disability occurred in 70.5% of patients. Pain intensity improved a mean of 4.1 points (from 7.1 to 3.0). This exceeds the threshold of 2 points for clinically meaningful improvement on the NRS.[28] Using this threshold as the cutoff, clinically meaningful improvement in pain intensity was seen in 73.9% of patients. Fear-avoidance beliefs improved 4.6 points (from 20.0 to 15.4). The mean self-rated percentage improvement was 77.2%. Thirty-nine percent of patients rated their improvement as excellent and another 50.0% rated their improvement as good. The mean number of visits, including those to a chiropractic physician and to a physical therapist, was 12.6.

Table 4 presents the main results from baseline to long-term follow-up. The mean duration of time from the end of treatment to long-term follow-up was 14.5 months. Mean self-rated improvement was 81.1%. Improvement was self-described as "good" or "excellent" in 80% of patients. Mean BDQ scores improved 31.0 points, NRS improved 4.2 points, and fear beliefs improved 4.5 points. The mean percentage improvement in scores on the BDQ was 67.4%. Clinically meaningful improvements in pain and disability were seen in 79% and 73% of patients, respectively.

The centralization sign was associated with improvement in disability at both the end of treatment (P = .0682) and long-term follow-up (P = .0225).

With respect to the relationship of fear-avoidance beliefs to clinical outcomes, we found that for each 1-U improvement in FABQ-Act score, BDQ improved by 0.83 points, a relationship that is statistically significant (P = .035). A 1-U improvement in FABQ-Act score was associated with a 0.02-U improvement in the NRS (P = .69) and with a 0.20-U change in self-rated percentage improvement (P = .64).

Two patients had surgery, one against the advice of the treating nonsurgical clinicians and the other because of progressive motor loss. The second patient had recurrence of LRSHD, which was treated nonsurgically with complete resolution.

The baseline data were compared between those patients in whom complete follow-up data were gathered and those with incomplete data. The only differences were with the baseline BDQ and NRS scores. Patients with incomplete data had a mean Bournemouth score of 55.3 (vs 44.6 for those with complete data) and a mean pain score of 8.7 (vs 6.9 for those with complete data). Neither of these reaches the threshold for clinically meaningful difference.

No major complications were seen in any patient. Increased pain after the initial distraction manipulation was seen in 6 patients (10%). This was resolved within 48 hours in all cases except one, in which it lasted 1 week and resolved. The increased pain was mild to moderate in all but one, in whom it was described as "severe." In this case, the increased pain was resolved within 48 hours. In all patients who experienced increased pain after manipulation, the reaction occurred after the first treatment in 5 and after the eighth treatment in 1. One patient reported increased pain after the initial stabilization exercise session, which resolved within 48 hours. Follow-up data were available in 5 of these patients. Of these, all reported their overall outcome as being "good" or "excellent." They improved by a mean of 32 points on the BDQ, a 66.6% improvement, and improved by a mean of 3 points on the NRS. Four of the 5 experienced clinically meaningful improvement in disability.

Discussion

Only a small percentage of patients with LRSHD ever require surgery.[3] Thus, it is essential that optimum nonsurgical approaches are developed, which bring about improvement in pain and disability as quickly as possible, reduce the likelihood of future problems, and minimize the need for surgical intervention. However, although a wide variety of nonsurgical treatments have been recommended for patients with LRSHD,[4] no individual treatment has been found to be most effective. Perhaps the largest trial of management of LRSHD is that of Weinstein et al[40] in which 501 patients were randomized to receive either surgery or nonsurgical intervention. Similar substantial improvements in pain and disability were found in both the surgical and nonsurgical groups. A high crossover rate in both groups limits interpretation of these data. In addition, the nonsurgical management was poorly described. Nonetheless, the study likely underestimated the effectiveness of nonsurgical management because patients were only included if they had already failed at least 6 weeks of initial nonsurgical care. Thus, patients who recovered with 6 weeks of nonsurgical management were not included in the study. An additional weakness of the Weinstein et al[40] study is that the nonsurgical management was not defined, because the treatment approaches taken were left up to the individual clinics involved in the study. It would be interesting to compare outcomes of surgical intervention with those of a well-defined nonsurgical approach such as what is reported here.

The current study supports the notion that nonsurgical management according to the DBCDR is a viable option for patients with LRSHD. Nearly 90% of patents reported their outcome to be either "excellent" or "good." Clinically meaningful improvement in disability was seen in more than 70% of patients, and clinically meaningful improvement in pain intensity was seen in 74% of patients. These improvements were maintained 14.5 months after cessation of treatment.

The fact that outcomes were as good or better at long-term follow-up is significant because it suggests that patients treated according to the DBCDR generally do not need ongoing "maintenance" or "supportive" care to maintain functional improvement. This may be due to the emphasis on education regarding beliefs, attitudes, and cognitions about spinal pain or the emphasis on the importance of continued exercise. The improvements in FABQ score at the end of treatment and long-term follow-up support the former; however, because compliance to home exercise was not measured, the latter can only be speculated upon.

When using the DBCDR, the clinician uses 3 questions of diagnosis. The first question relates to whether the patient has any symptoms or signs that may reflect a visceral problem or a serious or potentially life-threatening illness. The second question relates to where the pain is arising from. The third question then allows for investigation of factors that may be serving to perpetuate the pain experience. From this, individual treatment decisions are made based on the most important features in each case.

In this study, all patients had one thing in common with regard to question number 2—LRSHD. Because of this, nearly all patients were treated with distraction manipulation, which has been shown to reduce intradiscal pressure.[14,15] Neural mobilization was applied in all patients because this method attempts to mobilize the involved nerve root.[11] Eight patients were referred for ESI in an attempt to rapidly reduce nerve root pain. Although ESI generally brings about only temporary improvement,[41] it was felt in these patients that earlier commencement of more active treatments could begin if quick pain relief could be brought about with ESI. None of these 8 patients were treated solely with ESI. Because individual patients in the cohort may have had various other clinical features that were deemed relevant to each individual case, treatment approaches beyond those aimed at the disk or nerve root varied somewhat. These were based on specific features that were found in each individual patient.

In those patients whose symptoms centralized on examination, end-range loading maneuvers in the direction of centralization were provided.[18] Centralization of symptoms on end-range loading examination was found in 61.5% of patients. Two other studies assessed the presence of centralization signs in patients with confirmed LRSHD. Kopp et al[42] found that more than half (35 of 67) of patients with this condition centralized with end-range maneuvers. Alexander et al[43] found that approximately 42% (73 of 173) of LRSHD patients were centralizers. However, in both these studies, only extension was assessed and not flexion or lateral and rotational movements, as was the case in the present study. The protocol for end-range loading examination used in this study was more similar to that of Werneke and Hart,[44,45] who found that 77% of acute LBP patients[44] and 46% of chronic LBP patients[44] centralized on end-range loading examination. However, these studies included general cohorts of acute or chronic LBP patients; the subject populations were not limited to patients with LRSHD. As has been found previously,[46] peripheralization of symptoms on end-range loading examination appeared to carry a negative prognosis in the study reported here, although the percentage of peripheralizers (7%) was too low to allow for statistical analysis of this observation.

Joint manipulation was used in 6 patients, based on the presence of provocation of these LBP patients with segmental palpation and the absence of centralization on end-range loading examination. Several studies have found joint manipulation to be helpful in patients with LRSHD.[47,48] However, these studies did not use segmental pain provocation signs in the absence of centralization as the primary indication for this treatment modality.

Stabilization exercise was provided in 40 patients. The need for this was based on 3 clinical tests—the hip extension test,[49] the segmental instability test,[50] and the Active Straight Leg Raise test.[51] The stabilization exercise approach was adapted from that of Richardson et al[39] and McGill.[52] A number of studies have evaluated the effectiveness of this approach,[53] at least one of which involved patients with LRSHD.[54]

In cases in which CPH, fear, or catastrophizing were found, education and graded exposure[55,56] were the focus. Central to this process was education regarding the nature of CPH.[57] It was explained to these patients that the primary reason for their severe pain experience was that peripheral nociceptive signals were being amplified by the central nervous system before the arrival of these signals to the conscious aspect of the brain. Thus, fear of movement and catastrophizing, whereas understandable, were based on false, or exaggerated, information. Once the patient understood this, the graded exposure approach was begun. In the model of care evaluated in this study, if depression is suspected, this is monitored and the patient referred if poor response to treatment occurs, and it is deemed that the depression is relevant to this. As it turned out, this did not occur with any of the patients in this cohort.

The patients in this study improved with regard to pain and disability as well as with regard to fear beliefs. There was a statistically significant relationship between improvement in disability and improvement in fear beliefs. This is interesting in light of the fact that treatment was only provided by somatic-based clinicians—no professional psychologic intervention was provided. This suggests that, although psychologic processes such as fear and catastrophizing have been repeatedly found to play an important role in the perpetuation of spinal pain, it may be that somatic-based clinicians are often capable of managing this aspect of the clinical picture. Other studies have found that psychologic symptoms and signs improve with a purely somatic-based approach, especially when the approach involves self-care,[44] is focused on active exercise[58] and, particularly, if it is provided in a cognitive-behavioral context.[26,59-61] This does not preclude the possibility, however, that in some individual patients, the psychologic factors may be recalcitrant enough to require professional psychologic or psychiatric intervention.

It is interesting that improvements at the end of treatment appeared to be maintained at long-term follow-up. This may result from the emphasis of the approach on continuation of exercises and teaching self-management of acute episodes. However, compliance with exercise and self-care recommendations was not measured. Nonetheless, it does suggest that ongoing “maintenance” care is not necessary when treatment according to the DBCDR is used.

Seven patients (11.7%) reported increased pain related to the study treatments. This percentage is substantially less than the 30% to 34% that has been found in other studies of adverse reactions to treatment that involved manipulation.[62-64] Also, one study of short-term adverse reactions to manipulation found that patients with these reactions were less likely to experience a positive clinical outcome and were less satisfied with treatment.[63] In the study reported here, in those in whom follow-up data were available, the increase in pain did not appear to adversely affect their outcome, even with regard to self-rated improvement. This may be reflective of the emphasis on the use of distraction manipulation in this study or the focus on exercise designed to rapidly centralize and resolve the pain. However, the studies are not comparable enough to draw firm conclusions.

Patients were seen for a mean of 12.6 visits. This included examinations, reexaminations, treatment sessions, and exercise sessions. This number is consistent with other cohort studies of patients with radiculopathy treated according to the DBCDR.[7,8] It is likely that this represents the number of visits that are typically necessary to manage patients with LRSHD; however, this study design does not allow firm conclusions to be drawn.

Limitations

There are several important limitations to this study. One is the relatively small sample size, as well as the fact that complete follow-up data were not available on all patients. However, because no clinically meaningful differences were found between the group of patients in whom complete data were available and those in whom follow-up data were not available, it is not expected that the outcome would be different between these groups. The treatment occurred at a single practice setting. Therefore, it is not clear whether the findings are generalizable. Also, because this was a pragmatic study, that is, the patients were treated with a multimodal approach as would occur in usual clinical circumstances, it is impossible to determine the extent to which any individual treatment impacted outcome.

The pragmatic nature of the study is also one of its strengths. Because patients were treated as they would be during the usual course of clinical practice, as opposed to being treated in an experimental setting, the study reported "real world" outcomes, at least with regard to the "real world" environment in which this study took place. However, the findings cannot be generalized to clinical environments in which treatment protocols are used that do not strictly follow the DBCDR used in this study.

Also, the data were collected prospectively to avoid recall bias, and long-term follow-up was used. Strict diagnostic criteria were used to determine inclusion in the study. The inclusion of fear beliefs and complications provides useful clinical information that broadens the benefit of the information to nonsurgical clinicians who treat LRSHD. Although the observational design does not allow firm conclusions to be drawn with regard to efficacy, this design does allow conclusions to be drawn regarding safety.[65] However, because of this study's sample size, rare complications are not likely to be detected. Finally, the DBCDR upon which the management of these patients was based can be applied by any appropriately trained practitioner, increasing the generalizability of the findings.

Conclusion

Our findings suggest that patients with LRSHD who are treated according to a strict DBCDR tend to have favorable outcome to treatment. This favorable outcome appears to be maintained over the long term. Fear beliefs also appear to improve with the approach, and a significant relationship between improvement in disability and improvement in fear beliefs was found. The absence of a control group does not allow firm conclusions to be drawn, but further research in the form of large cohort studies and randomized, controlled trials would be beneficial in determining the efficacy of this treatment approach in patients with LRSHD. The treatments used in the study appear to be safe in this patient population.

Practical Applications

- Lumbar radiculopathy secondary to herniated disk is a common reason for spine surgery, and little is known about nonsurgical options.
- A DBCDR has been developed to provide nonsurgical spine clinicians with a model of diagnostic and treatment decision making.
- This approach was applied to a cohort of patients diagnosed with LRSHD.
- In this study, clinically meaningful improvement in pain was found in 79% of patients, and clinically meaningful improvement in disability was found in 70% of patients.
- Treatment according to a DBCDR may have promise in the nonsurgical management of patients with LRSHD.

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No funding sources or conflicts of interest were reported for this study.

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